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10/726,400	12/03/2003	Kenneth A. Jones	AQMED.0102	5601
22858	7590	12/26/2007		
CARSTENS & CAHOON, LLP			EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary

Application No.

10/726,400

Applicant(s)

JONES ET AL.

Examiner

Leslie R. Deak

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 12-17, 27-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 9-11 and 18-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 7, 9-11, and 18-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant claims in claim 7 that the valve comprises a first and second inlet and an outlet wherein each of the inlets and the outlet comprise a "coupling means." The specification as originally filed does not support the limitation drawn to the "coupling means." Furthermore, the term "coupling means" does not appear in the originally filed claims. For the purposes of examination, the Examiner is interpreting the claimed "coupling means" to comprise tubing lines 118, 122, as illustrated in FIG 3. Appropriate correction is required.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 sets forth that "the source" is a reservoir that is open to the atmosphere. The parent claim, claim 7, specifically claims that the second inlet

comprises a flow control device that passes fluid from the source into the valve while preventing entry of air into the valve. It is unclear to the Examiner how a valve may operate in such a manner when the source is open to the atmosphere, or ambient air. It is the position of the Examiner that for the purposes of claim 25 the valve merely operates as a pressure relief valve that does not prevent air from entering the valve, since the source is connected to the atmosphere.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the expelling outlet set forth in claim 22 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 25, as interpreted by the Examiner, are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,707,356 to Paul in view of US 6,315,752 to DiMatteo.

In the specification and figures, Paul discloses the apparatus substantially as claimed by applicant. Paul discloses a pressure relief valve that is designed for use during heart surgery in an extracorporeal circuit (see column 2, lines 8-46). The valve 10 comprises a body 12 with a first inlet 14 with an axis parallel to the direction of flow (see arrow in FIG 1) and a coupling means in the form of line 44 connecting the valve to the patient (see FIG 6). The valve further comprises a second inlet 47 with an axis parallel to flow through the inlet, and an outlet 16 with an axis parallel to flow (see FIGS 1-2, column 3, column 4, lines 16-33) and a tubing line 42 connecting the outlet to pump 48 (see FIG 6). First inlet 14 comprises a one-way duckbill valve 18 that is capable of allowing fluid from a patient's body towards the outlet (see FIG 3). The second inlet 47

comprises a coupling 32 and a two-way valve 32 that comprises inlet umbrella 34 and outlet umbrella 36 that is capable of allowing fluid to pass from a source into the valve body towards the outlet in the event of a negative pressure situation and outward from the valve into the source 47 in the event of a positive pressure situation (see column 3).

Paul fails to disclose that the first and second inlet are disposed at an angle of less than 90 degrees, but does disclose that various flow axes are contemplated within the scope of the invention (see column 4, lines 40-41). However, DiMatteo discloses a bypass graft that passes blood through the lumens of tubes 200, 210. The inlet lumens at 211, 202 are disposed at an acute angle, that is less than 90 degrees, in order to reduce turbulence between the flows entering from both lumens (see FIG 2, column 4, lines 7-15). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to arrange the inlets of the Paul device to have less than 90 degrees between them as disclosed by DiMatteo in order to reduce turbulence in the flow through the main lumen, as taught by DiMatteo.

8. Claims 7, 10, 11, 23, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,707,356 to Paul in view of US 6,315,752 to DiMatteo, further in view of US 7,033,336 to Hogendijk.

In the specification and figures, Paul discloses the apparatus substantially as claimed by applicant. With regard to claims 7, 10, and 26, Paul discloses a pressure relief valve that is designed for use during heart surgery in an extracorporeal circuit (see column 2, lines 8-46). The valve 10 comprises a body 12 with a first inlet 14 with an axis

parallel to the direction of flow (see arrow in FIG 1) and a coupling means in the form of line 44 connecting the valve to the patient (see FIG 6). The valve further comprises a second inlet 47 with an axis parallel to flow through the inlet, and an outlet 16 with an axis parallel to flow (see FIGS 1-2, column 3, column 4, lines 16-33) and a tubing line 42 connecting the outlet to pump 48 (see FIG 6). First inlet 14 comprises a one-way duckbill valve 18 that is capable of allowing fluid from a patient's body towards the outlet (see FIG 3). The second inlet 47 comprises a two-way valve 32 that comprises inlet umbrella 34 and outlet umbrella 36 that is capable of allowing fluid to pass from a source into the valve body towards the outlet in the event of a negative pressure situation and outward from the valve into the source 47 in the event of a positive pressure situation (see column 3).

Paul fails to disclose that the first and second inlet are disposed at an angle of less than 90 degrees, but does disclose that various flow axes are contemplated within the scope of the invention (see column 4, lines 40-41). However, DiMatteo discloses a bypass graft that passes blood through the lumens of tubes 200, 210. The inlet lumens at 211, 202 are disposed at an acute angle, that is less than 90 degrees, in order to reduce turbulence between the flows entering from both lumens (see FIG 2, column 4, lines 7-15). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to arrange the inlets of the Paul device to have less than 90 degrees between them as disclosed by DiMatteo in order to reduce turbulence in the flow through the main lumen, as taught by DiMatteo.

Paul and DeMatteo fail to disclose that the second inlet comprises a coupling means for coupling the second inlet to a source and that the flow control device is capable of preventing the entry of air into the valve. However, Hogendijk discloses a catheter assembly with a first inlet 258 and a second inlet 224, and an outlet passage 213 wherein the second inlet is coupled to a venous return line 224 (see column 7, lines 45-67, column 8 lines 1-8, FIG 6C). The second inlet is regulated by a valve 256 that opens if the negative pressure in outlet line 213 is too great, allowing for pressure relief such that high levels of suction-related aspiration will not harm the patient's vessel (see column 3, lines 45-50). Tubing 224 connected to the relief valve may, in the alternative, be connected to a fluid source such as saline (see column 10, lines 15-20). It would have been obvious to one having ordinary skill at the time of invention to couple a venous reservoir or other source of fluid to the pressure relief portion of the valve suggested by Paul and DeMatteo in order to provide a sterile fluid source to relieve excess pressure, in order to prevent suction-related harm to the patient's vessel, as taught by Hogendijk. Taken together, the references reasonably suggest a relief valve with inlets and outlets disposed at acute angles to one another wherein the relief portion is coupled to a fluid source.

With regard to claims 11 and 23, applicant claims only that the opening pressures of the valves may be modified. Paul discloses that the valve umbrellas are operable to open at particular pressures (see column 4, lines 16-34). It has been held that the mere recitation of adjustability, where needed, is not a patentable advance. See MPEP 2144.04(V)(D). It is the position of the examiner that the opening pressure of the

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valves may be adjusted as a part of the manufacturing process, forming the umbrella structure of a more or less resilient material in order to adjust the opening pressures of the valves. Since the valve disclosed by Paul is capable of being adjusted, or changed, to modify the opening pressures, the disclosures of the cited prior art meet the limitations of the claims.

9. Claims 9, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,707,356 to Paul in view of US 6,315,752 to DiMatteo in view of US 7,033,336 to Hogendijk, further in view of US 5,158,539 to Kolff et al

In the specification and figures, the prior art suggests the apparatus substantially as claimed by applicant with the exception of a transparent window and visual indicator of fluid flow. With regard to claims 9 and 18, Kolff discloses a valve for preventing air aspiration in cardiopulmonary bypass patients wherein the valve member and the tubing lines connected thereto are made of a transparent material, thereby providing a window into the valve and a visual indicator of fluid flow. It has been held to be within the skill of a worker in the art to select a known material on the basis of its suitability for the intended purpose. See MPEP 2144.07. In the instant case, it would have been obvious to one having ordinary skill in the art at the time of invention to form the valve suggested by the prior art of a transparent material in order to provide a transparent window into the valve and a visual indicator of fluid flow within the valve.

With regard to claim 19, Paul discloses that umbrella section 35a of valve 35 (see FIG 2), may deform in response to pressure through valve 32, thereby providing a mechanical indicator of flow within the valve.

10. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,707,356 to Paul in view of US 6,315,752 to DiMatteo in view of US 7,033,336 to Hogendijk, further in view of US 4,747,826 to Sassano.

In the specification and figures, the prior art suggests the device substantially as claimed by applicant (see rejection above) with the exception of an electronic flow detector connected to a visual display. Sassano discloses a fluid flow system for rapid venous infusion that comprises tubing, valves, and means for sensing fluid flow. The device comprises fluid flow controllers 38 (which may include valves) and monitors coupled to infusion pump 14 (see column 4, lines 14-26). The flow sensors are electronic in nature and have a corresponding visual display (see column 6, lines 23-30). The system, including its sensors and controllers, allow for rapid, automated infusion to a patient that can be monitored by an operator consulting the display (see column 2, lines 16-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to couple an electronic fluid sensor with visual display, as disclosed by Sassano, with the valve suggested by the prior art in order to provide for easy fluid flow monitoring by a single operator, as taught by Sassano.

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,707,356 to Paul in view of US 6,315,752 to DiMatteo in view of US 7,033,336 to Hogendijk, further in view of US 6,142,980 to Schalk et al.

In the specification and figures, the prior art suggests the apparatus substantially as claimed by applicant (see rejection above) with the exception of an additional expelling outlet. Schalk discloses a pressure relief valve with an inlet and outlet for blood flow, a positive pressure relief valve, and a vacuum relief valve (see column 1, lines 35-55). Paul discloses that the positive pressure relief and vacuum relief valve are integrated into a single housing. Schalk discloses a valve with four ports including an expelling outlet, and the prior art suggests the rest of the elements of the claim. It is the position of the examiner that the addition of an expelling port as disclosed by Schalk on the valve device suggested by the prior art provides only the expected result of having a second positive pressure relief valve. Applicant fails to disclose or suggest that the second expelling port solves any particular problem or provides any unexpected results. Accordingly, it is the position of the Examiner that the addition of the expelling port as claimed by applicant does not patentably distinguish the instantly claimed valve over the suggestions of the prior art.

Response to Arguments

12. Applicant's amendments and arguments filed 15 October 2007 have been entered and fully considered.

13. Applicant's amendment to claim 9 has rendered moot the objection presented in the prior office action. Accordingly, the objection has been withdrawn.

14. Applicant's arguments with regard to the pending claims are moot in light of the new grounds of rejection presented above. Nonetheless, the Examiner wishes to address Applicant's arguments that are pertinent to the instant rejection.

15. With regard to claims 7, 10, and 26, Applicant argues that Paul teaches an "ambient air conduit" as the relief valve, which teaches away from providing a coupling to another fluid source in order to provide pressure relief, as claimed by applicant. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, it is the position of the Examiner that the "ambient air conduit" disclosed by Paul is not incapable of being coupled to another fluid source to provide pressure relief, and the connection to ambient air is merely a preferred embodiment of the Paul device. The conduit disclosed by Paul comprises a tubing element 32 that is capable of being connected to another fluid source, as disclosed by Hogendijk. Taken together, the disclosures of Paul and Hogendijk suggest a flow controller with a one-way flow control and two-way pressure relief valve that may be connected to a fluid source, preventing tissue damage in the event of excess positive or negative pressure within the flow line.

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16. With regard to claims 9, 11, and 18- 25, Applicant argues that the dependent claims stemming from a non-obvious independent claims should be considered nonobvious as well. However, it is the position of the Examiner that independent claim 7 is an obvious variation of the prior art of record, rendering it and its dependent claims unpatentable over the prior art.

Conclusion

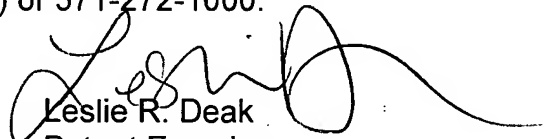
17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Leslie R. Deak
Patent Examiner
Art Unit 3761
11 December 2007